**ABSTRACT**

As part of an FDA tobacco product application, FDA guidance recommends that applicants evaluate adult behavioral intentions toward the candidate tobacco product, including trial, dual use, and switching intentions. Altria Client Services (ALCS) previously developed and validated behavioral intention (BI) scales to support future FDA filings for an e-vapor product. However, the psychometric properties of these scales when modified to reference other tobacco product categories have not been evaluated. Therefore, the current study was designed to determine whether the BI scales are valid when modified to reference an oral TDN containing product and a MST product.

Data were derived from two previously conducted studies, whereby the BI scales were modified to specify an oral TDN (Study 1: N=1168) and an MST product (Study 2: N=871). These studies included current, never, and former tobacco product users. Rasch modeling and classical test theory approaches were utilized to evaluate rating scale functioning, unidimensionality, reliability, validity, and bias related to item dimension. Additionally, DIF analyses were conducted to determine whether item functioning was substantially different across tobacco product categories (i.e., e-vapor, oral TDN, MST). For both Study 1 and Study 2, Rasch analyses revealed that the BI items exhibited Likert-type rating scales functioning appropriately. Results provided strong evidence for unidimensionality, excellent internal consistency reliability, and convergent validity. Rash-based DIF analyses did not suggest substantial bias based on age, race, gender, or tobacco use status. Finally, DIF analyses revealed that the BI scales functioned similarly across tobacco product categories (i.e., e-vapor, oral TDN, MST). These results provide strong evidence that the BI scales can continue to exhibit strong psychometric properties when modified to reference other tobacco products, namely, an oral TDN and an MST product. Future research could evaluate the predictive validity of these scales.

**METHODS**

**BEHAVIORAL INTENTION SCALES**

- **Phase 1**: Study 1 was conducted to evaluate the psychometric properties of the behavioral intention items when modified to reference an oral TDN and MST product.
- **Phase 2**: Study 2 was conducted to evaluate the psychometric properties of the behavioral intention items when modified to reference an oral TDN and MST product.

**PHASE 1 DATA SOURCES**

- Data for Phase 1 were derived from two previously conducted studies, whereby the BI scales were modified to specify an oral TDN (Study 1: N=1168) and an MST product (Study 2: N=871).

**PHASE 2 DATA SOURCES**

- Data for Phase 2 included the 2 data sources for Phase 1, as well as data from a 4-week substudy, whereby the BI scales were developed and validated specifying an e-vapor product. This study (Study 2) included behavioral intention data (N=343) from the following five groups:
  1. adult smokers planning to quit in the next 30 days (AS)
  2. adult smokers not planning to quit in the next 30 days (ASNPQ)
  3. adult former tobacco users (Former)
  4. adult never tobacco users (Never)

**REFERENCES**


**ANALYTIC PLAN**

**Phase 1: Evaluation of the scales’ psychometric properties when modified to reference oral TDN and MST**

- To determine whether the Behavioral Intention scales are valid to specify these tobacco products, Rasch modeling and classical test theory approaches were utilized to evaluate:
  1. Rasch scale functioning—evaluation of response option thresholds through a partial credit model (Rao, Masters, 1982)
  2. Reliability—internal consistency reliability (Cronbach’s alpha) and Rasch-derived reliability (person reliability)
  3. Validity—Pearson correlations between the Behavioral Intention scales and a purchase intent metric
  4. Classical test theory analyses (e.g., Cronbach’s alpha, convergent validity). Data were randomly split into validation and cross-validation samples to confirm findings were stable across sampling.

**Phase 2: Evaluation of item functioning across tobacco product categories**

- DIF analyses were conducted to control for item functioning that was substantially different across tobacco product categories (e.g., when the items referenced an e-vapor product, an oral TDN product, or an MST product).